UNITED STATES DISTRICT COURT

DISTRICT OF MAINE

AROOSTOOK MEDICAL CENTER, Plaintiff v. MICHAEL O. LEAVITT,[1] in his official capacity as SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendant	Civil No. 04-134-P-C

Gene Carter, Senior District Judge

ORDER GRANTING IN PART PLAINTIFF'S MOTION FOR JUDGMENT BASED ON THE ADMINISTRATIVE RECORD AND DENYING DEFENDANT'S MOTION FOR JUDGMENT BASED ON THE ADMINISTRATIVE RECORD

Plaintiff Aroostook Medical Center (hereinafter "AMC") commenced this action against the Secretary of the United States Health and Human Services Department (hereinafter "Secretary") alleging that the Provider Reimbursement Review Board (hereinafter "the Board") arbitrarily and capriciously denied Plaintiff's request for increased payments under federal Medicare law.[2] Judicial review of the Board's final decision is available pursuant to 42 U.S.C. § 1395oo(f).[3]

[1] Plaintiff's Complaint names Tommy G. Thompson as the Defendant in this action. Pursuant to Fed. R. Civ. P. 25(d)(1), Michael O. Leavitt is now the proper Defendant.

[2] The Secretary did not grant AMC's petition for further review, thus making the Board's decision final and subject to judicial review.

[3] 42 U.S.C. § 1395oo(f) provides as follows:

Both parties have now moved for Judgment Based on the Administrative Record. *See* Plaintiff's Motion for Judgment Based on the Administrative Record (Docket Item No. 13) and Defendant's Motion for Judgment Based on the Administrative Record (Docket Item No. 16). Plaintiff filed a response to Defendant's Motion (Docket Item No. 21). For the reasons set forth below, the Court will deny Defendant's Motion, grant Plaintiff's Motion in part, and remand this matter to the Board for further proceedings.

I. Facts and Procedural History

AMC is a general acute care hospital located in Presque Isle, Maine. Among its services, AMC provides end stage renal dialysis (hereinafter "ESRD") to patients suffering from kidney ailments. Rates paid to ESRD facilities under federal Medicare law are established by the Centers for Medicare and Medicaid Services (hereinafter "CMS"),[4] and payments are made on a prospective basis. 42 C.F.R. § 413.174. Subject to meeting certain qualifying criteria, an ESRD provider may request that CMS "approve an exception to that rate and set a higher prospective payment rate." 42 C.F.R. § 413.180. At issue in this case is the following regulation:

> CMS may approve exceptions to an ESRD facility's prospective payment rate if the facility demonstrates, by convincing objective evidence, that its total per treatment costs are reasonable and allowable under the relevant cost reimbursement principles of part 413 and that its per treatment costs in excess of its payment rate are directly attributable to any of the following criteria:

> Providers shall have the right to obtain judicial review of any final decision of the Board, or of any reversal, affirmance, or modification by the Secretary, by a civil action commenced within 60 days of the date on which notice of any final decision by the Board or of any reversal, affirmance, or modification by the Secretary is received. … Such action shall be brought in the district court of the United States for the judicial district in which the provider is located.

[4] On July 1, 2001, the Health Care Financing Administration changed its name to the Centers for Medicare and Medicaid Services.

…

(b) Isolated essential facility, as specified in § 413.186.

42 C.F.R. 413.182. To qualify for an exception as an isolated essential facility, AMC must meet three criteria:

(1) The facility must be the only supplier of dialysis in its geographical area;

(2) The facility's patients must be unable to obtain dialysis services elsewhere without substantial additional hardship; and

(3) The facility's excess costs must be justifiable.

42 C.F.R. 413.186(a). Facilities may only apply for exceptions to the standard rates during specifically designated periods.[5] The federal regulations set forth documentation requirements for ESRD facilities seeking increased payments,[6] and additional

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[5] A facility must request an exception to its payment rate within 180 days of --

(1) The effective date of its new composite payment rate(s);

(2) The effective date that CMS opens the exceptions process; or

(3) The date on which an extraordinary cost-increasing event occurs, as specified (or provided for) in §§ 413.182(c) and 413.188.

42 C.F.R. 413.180(d)

[6] 42 C.F.R. 413.180 provides in pertinent part:

(f) Documentation for a payment rate exception request. If the facility is requesting an exception to its payment rate, it must submit to CMS its most recently completed cost report as required under § 413.198 and whatever statistics, data, and budgetary projections as determined by CMS to be needed to adjudicate each type of exception. CMS may audit any cost report or other information submitted. The materials submitted to CMS must--

(1) Separately identify elements of cost contributing to costs per treatment in excess of the facility's payment rate;

(2) Show that the facility's costs, including those costs that are not directly attributable to the exception criteria, are allowable and reasonable under the reasonable cost principles set forth in this part;

(3) Show that the elements of excessive cost are specifically attributable to one or more conditions specified in § 413.182;

documentation requirements for payment requests resulting from isolated and essential status.[7]

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(4) Specify the amount of additional payment per treatment the facility believes is required for it to recover its justifiable excess costs; and

(5) Specify that the facility has compared its most recently completed cost report with cost reports from (at least 2) prior years. The facility must explain any material statistical data or cost changes, or both, and include an explanation with the documentation supporting the exception request.

(g) Completion of requirements and criteria. The facility must demonstrate to CMS's satisfaction that the requirements of this section and the criteria in § 413.182 are fully met. The burden of proof is on the facility to show that one or more of the criteria are met and that the excessive costs are justifiable under the reasonable cost principles set forth in this part.

[7] Specifically, the regulations require the following:

(c) Documentation.

(1) Isolated. Generally, to be considered isolated, the facility must document that it is located outside an established Metropolitan Statistical Area and provides dialysis to a permanent patient population, as opposed to a transient patient population.

(2) Essential. To be considered essential, the facility must document –

(i) That a substantial number of its patients cannot obtain dialysis services elsewhere without additional hardship; and

(ii) The additional hardship the patients will incur in travel time and cost.

(3) Cost per treatment. The facility must –

(i) Document that its cost per treatment is reasonable; and

(ii) Explain how the facility's cost per treatment in excess of its composite rate relates to the isolated essential facility criteria specified in paragraph (b) of this section.

(4) Additional information. The facility must also furnish the following information in a format that concisely explains the facility's cost and patient data to support its request:

(i) A list of current and requested payment rates for each modality.

(ii) An explanation of how the facility's costs in excess of its composite rate payment are attributable to its being an isolated essential facility.

(iii) An explanation of any unusual geographic conditions in the area surrounding the facility.

(iv) A copy of the latest filed cost report and a budget estimate for the next 12 months prepared on cost report forms.

(v) An explanation of unusual costs reported on the facility's actual or budgeted cost

On March 1, 2000, a window opened for providers to submit rate exception requests. The current default rate paid at this time was $122.62 for each hemodialysis treatment. On August 23, 2000, AMC timely filed such a request, invoking the exception category of "isolated essential facility." As required by the federal regulations, AMC submitted its petition to a Fiscal Intermediary (hereinafter "Intermediary"),[8] requesting a per-treatment payment of $227.58. Administrative Record at 509. The Intermediary recommended that CMS grant the exception, but at the reduced rate of $218.97. Administrative Record at 629. The Intermediary suggested the lower rate because AMC did not identify or explain discrepancies between its year 1999 and year 2001 budgets; thus, the Intermediary recommended that the lower of the two fiscal budgets be used as the baseline number for quantifying the exception. Administrative Record at 629.

The Intermediary submitted its recommendation to the CMS for an administrative determination of whether the exception was warranted. By letter dated November 3, 2000, CMS declined to adopt the Intermediary's recommendation, concluding that

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> reports and any significant changes in budgeted costs and data compared to actual costs and data reported on the latest filed cost report.
>
> (vi) The name, location of, and distance to the nearest renal dialysis facility.
>
> (vii) A list of patients by modality showing commuting distance and time to the current and the next nearest renal dialysis facility.
>
> (viii) The historical and projected patient-to-staff ratios and number of machines used for maintenance dialysis treatments.
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> (ix) A computation showing the facility's treatment capacity, arrived at by taking the total stations multiplied by the number of hours of operation for the year divided by the average length of a dialysis treatment.
>
> (x) The geographic boundaries and population size of the facility's service area.

42 C.F.R. 413.186.

[8] The Fiscal Intermediary in this case was BlueCross BlueShield Association/Associated Hospital Service of Maine.

although AMC is both isolated and essential, it failed to link its increased costs with its isolated and essential status. CMS outlined several apparent deficiencies in AMC's petition for an exception. First, CMS indicated that AMC did not properly delineate the distance from each patient's home to the nearest facility in Bangor. Second, AMC did not adequately document required travel costs for the medical director of Northeast Nephrology.[9] Third, CMS determined that AMC's reported supply delivery charges and freight charges contained inconsistencies or were not sufficiently documented. Fourth, CMS determined that AMC's claim for increased overhead charges due to economies of scale was not properly explained. Fifth, CMS indicated that AMC did not adequately document its increased nursing costs due to local nonavailability. Sixth, CMS concluded that AMC's decision not to purchase reusable dialyzers, which resulted in increased supply costs, was a management decision and not a function of location. Seventh, CMS attributed AMC's hardware/software costs -- incurred to allow better communication with physicians at Eastern Maine Medical Center -- to the fact that it does not have a full-time Medical Director. As a result of these purported deficiencies, CMS declined to adopt the Intermediary's recommendation and denied AMC's exception request.[10] *See* Administrative Record at 498-500.

AMC timely filed a request for hearing before the Provider Reimbursement Review Board. In support of its hearing before the Board, AMC requested that the Board subpoena Mark Horney, whom AMC alleges was the CMS employee responsible for reviewing AMC's exception request. CMS opposed the subpoena of Mr. Horney on the

[9] The administrative record reflects that the medical director would travel to AMC from Bangor two days every two weeks.

[10] The estimated Medicare reimbursement impact is $625,000. Administrative Record at 636.

grounds that CMS's decision was an agency decision and not an individual decision, thus making Mr. Horney's testimony unnecessary. Further noting Mr. Horney's unavailability, CMS indicated it would make available a substitute witness, Michael Powell, who would testify about the policies and procedures pertaining to AMC's application. The Board denied the subpoena request, stating that Mr. Horney's testimony was not necessary in light of the availability of Mr. Powell's testimony, and that AMC's request for all records or materials consulted or prepared in reviewing the exception request are covered by the deliberative process privilege, 5 U.S.C. § 552(b)(5). Administrative Record at 848.

AMC also requested that the Board subpoena Michael Nobile, the representative of the Intermediary who recommended granting the exception request.[11] CMS opposed this subpoena on the ground that the Intermediary only provided a recommendation to CMS, thus the processes and rationale employed by Mr. Nobile were not relevant to resolution of the exception request. The Board agreed, ruling that "the testimony of Michael Nobile is not material and relevant to the issue of whether the Provider is entitled to an exception to the composite rates for End State Renal Disease (ESRD). Mr. Nobile did not make the final decision as to whether the Provider was entitled to an ESRD exception." Administrative Record at 896-97. Upon motion for reconsideration, the Board reaffirmed its refusal to issue the subpoena. Administrative Record at 847. Subsequently, the Board affirmed the decision reached by CMS denying AMC's application for relief from the composite payment rate. *See Aroostook Medical Ctr. v. Assoc. Hosp. Serv. of Me.*, 2004 WL 2066683 (P.R.R.B. June 9, 2004).

[11] In addition to requesting that Mr. Nobile appear at the hearing to testify, AMC also sought a subpoena for all records and other materials that Mr. Nobile reviewed, consulted, or prepared during his review of AMC's exception application. *See* Administrative Record at 894.

II. Standard of Review

In providing for judicial review of Provider Reimbursement Review Board decisions, 42 U.S.C. § 1395oo(f) mandates that review be conducted "pursuant to the applicable provisions under chapter 7 of Title 5 notwithstanding any other provisions in section 405 of this title." *Id.* Pursuant to 5 U.S.C. § 706(2)(A), this Court can only set aside the decision of the Board if that decision is "arbitrary, capricious, and abuse of discretion, or otherwise not in accordance with law." *Id.*; *see also S. Shore Hosp., Inc. v. Thompson*, 308 F.3d 91, 97 (1st Cir. 2002). Bearing in mind this deferential review standard, the Court turns to the issues raised in this case.

III. Discussion

In its Motion for Judgment Based on the Administrative Record, AMC contends that the Board's denial of the subpoena requests amounted to a denial of due process. *Id.* at 17. Specifically, AMC states that "the Provider was prevented from creating an appropriate administrative record," *id.*, and "the Board prevented the Plaintiff from obtaining the documents that the PRM [Provider Reimbursement Manual[12]] required the Intermediary to prepare during its review." *Id.*

The issuance of subpoenas in ESRD exception cases is governed by the following federal regulation:

> When reasonably necessary for the full presentation of a case, the Board may, either upon its own motion or upon the request of a party, issue subpoenas for the attendance and testimony of witnesses and for the production of books, records, correspondence, papers, or other documents which are relevant and material to any matter in issue at the hearing. Parties who desire the issuance of a subpoena shall, not less than 10 days prior to the time fixed for the hearing, file with the Board a written request therefor, designating the witnesses or documents to be produced, and

[12] The Provider Reimbursement Manual is a set of guidelines promulgated by CMS and used in this case for determining eligibility for ESRD rate exceptions.

> describing the address, or location thereof with sufficient particularity to permit such witnesses or documents to be found. The request for a subpoena shall state the pertinent facts which the party expects to establish by such witnesses or documents and whether such facts could be established by other evidence without the use of a subpoena. Subpoenas, as provided for above, shall be issued in the name of the Board, and the Centers for Medicare & Medicaid Services shall assume the cost of the issuance and the fees and mileage of any witness so subpoenaed, as provided in section 205(d) of the Act, 42 U.S.C. 405(d).

42 C.F.R. § 405.1857. The Court is satisfied that the subpoena requested for Mr. Nobile complied with the above cited regulation and was necessary to ensure that AMC had a full and fair opportunity to present its position to the Board.[13] Federal law requires that Board review of CMS's decisions include full consideration of evidence presented to the Intermediary, to wit: "A decision by the Board shall be based upon the record made at such hearing, which shall include the evidence considered by the intermediary and such other evidence as may be obtained or received by the Board, and shall be supported by substantial evidence when the record is viewed as a whole." 42 U.S.C. § 1395oo(d).

The Court further notes that CMS's own regulations place the burden of identifying any omissions in an exception request with the Intermediary. "The intermediary reviews the exception request, the cost report, the facility's projected costs, and any other documentation submitted by the facility to assure that it is complete and accurate. If the renal facility fails to submit the required documentation, as required by this chapter, the exception request is returned to the facility." Provider Reimbursement Manual – Part I, § 2723.3(A), *available at*

[13] The Board's decision to deny AMC's request for an exception was based in large part on the purported failure of AMC to submit cost reports and to adequately document commuting distances from the patients' residences to the Bangor facility. It is undisputed that AMC submitted the so-called "I series" -- the cost report worksheets related to the dialysis unit. AMC contends that because these documents contain all of the necessary information for the Intermediary to make a recommendation, AMC complied with the cost report requirement. Moreover, AMC contends that the Intermediary already had a copy of the latest cost report at the time the exception request was filed.

http://www.cms.hhs.gov/manuals/pub151/pub_15_1.asp. In this case, the Intermediary never notified AMC that there were deficiencies in its application. Instead, the Intermediary calculated its own exception rate, different from what AMC requested, and presented this recommendation to CMS.

Because the Intermediary made calculations and conclusions based on the materials submitted to it by AMC, and because 42 U.S.C. § 1395oo(d) requires all evidence considered by the Intermediary to be presented to the Board, the Court concludes that the Board abused its discretion in failing to issue a subpoena for Mr. Nobile to appear at the Board hearing with the documents he considered. The Board's denial of the subpoena request deprived AMC of the opportunity to present a full and complete argument to the Board. Furthermore, CMS and the Board rejected AMC's application on largely technical grounds, yet the record does not reflect that the Intermediary ever notified AMC of any omissions or other shortcomings in its request. Mr. Nobile's testimony, and the documents considered by the Intermediary, are highly relevant in resolving the disputes related to the cost report and other issues pertaining to the merits of AMC's request.

In contrast, the Court does not find an abuse of discretion in the Board's decision not to subpoena Mr. Horney. The Court is satisfied that Mr. Powell was well qualified to testify as a representative of CMS. The Court, reviewing only for abuse of discretion, cannot undo a decision of the Board that was reasonable at the time it was made. The fact that Mr. Powell may not have testified at the hearing to AMC's satisfaction does not provide this Court with a proper basis to vacate this decision.

Although the Court finds error in the fundamental fairness and due process afforded to AMC, the Court does not reach the issue of whether AMC's documented costs are related to its isolated essential status and whether the exception request should be approved.[14] On remand, the Board shall subpoena the testimony of Mr. Nobile and allow AMC a full and fair opportunity to present its claim before the Board.

IV. Conclusion

For the reasons set forth above, it is **ORDERED** that the decision of the Provider Reimbursement Review Board be, and it is hereby, **VACATED**. It is **FURTHER ORDERED** that this case be, and it is hereby, **REMANDED** to the Provider Reimbursement Review Board for further proceedings consistent with this opinion.

/s/Gene Carter

GENE CARTER
United States Senior District Judge

Dated at Portland, Maine this 13th day of April, 2005.

[14] However, the Court notes that the Board's conclusion that AMC failed to submit adequate documentation concerning patient commuting distances borders on arbitrary and capricious. Elementary arithmetic would allow for computation of any alleged deficiencies in AMC's evidence. The record indicates that the distance from AMC to the next nearest facility in Bangor is 160 miles. AMC provided the distance each patient must travel to the AMC facility, but not to the Bangor facility. Simply subtracting the number of miles a patient had to travel to AMC from 160 would present the minimum number of miles a patient had to travel to the Bangor facility. Denial of AMC's exception request on this minor technicality is, as AMC suggests, a matter of form over substance.

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